

### **REMARKS**

Applicants respectfully request entry of the Amendment and reconsideration of the claims.

Please cancel claims 11-12, and 36-43 without prejudice or disclaimer. Applicants reserve the right to file one or more continuation applications claiming the cancelled subject matter.

Applicants have amended claims 1-10, 13-15, 17, 19, 21, 24, 28, 33, and 35. Support for this amendment is found throughout the specification including at page 10, page 14, lines 1-19; page 15, lines 23-26; and page 18, line 1-11.

Applicants have added new claims 44-47. Applicants submit that the new claims are supported throughout the specification including at page 17, lines 18-23; page 18, lines 1-11; and page 20, lines 1-14.

### **Interview Summary**

Applicants thank Examiner Getzow for the interview on September 4, 2008. We discussed the 103 rejections of record.

### **Rejection under 35 U.S.C. § 112, second paragraph**

The Examiner rejects claims 9-11 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness over the term “the controller”. Claim 11 has been cancelled rendering the rejection of this claim moot. While not acquiescing to the rejection of claims 9-10, Applicants have amended the claims so that they no longer refer to “the controller”. In view of the foregoing, Applicants respectfully assert that rejection has been overcome and request removal of the rejection under 35 U.S.C. § 112, second paragraph.

### **Rejections Under 35 U.S.C. § 103(a)**

The Examiner rejected claims 1-43 under 35 U.S.C. § 103(a) as being obvious over Freed et al. (U.S. Patent No. 5,891,185) in view of Sanders (U.S. Patent No. 5,897,579). Claims 11-12, and 36-43 have been cancelled rendering the rejection of the claims moot. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

The recent Supreme Court case, *KSR Int 'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007), sets forth the legal standard for obviousness. This case reaffirms the analytical framework set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), which mandates that an objective obviousness analysis includes: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; and (3) resolving the level of ordinary skill in the pertinent art. *Id.* at 1734. Secondary considerations such as commercial success, long felt but unsolved needs, or failure of others may also be persuasive.

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a prima facie case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. *Id.* at 1445. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *See Oetiker*, 977 F.2d at 1445. One criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that claimed subject matter should be carried out and would have a reasonable likelihood of success viewed in light of the prior art. *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

“It remains important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). “Hindsight” is inferred when the specific understanding or principal within the knowledge of one of ordinary skill in the art leading to the modification of the prior art in order to arrive at appellant’s claimed invention has not been explained. *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998).

Applicants submit that the cited references do not disclose all of the elements of the claims and any modification of the Freed patent with the teaching of Sanders would result in opening the airway, which is very dangerous for swallowing.

Applicants claim 1 is directed to a method to coordinate control of movements in the upper airway during activities such as swallowing in a subject, comprising: a)implanting at least two intramuscular stimulators into the thyrohyoid muscle and at least one other hyoid muscle involved in the upper airway and vocal tract of the subject)b)implanting a signal generator in the

subject that generates electrical pulses to at least two intra-muscular stimulators at a frequency of about 10 to 75 Hz; wherein electrical pulses from the signal generator activate at least two muscles to produce the coordinate movement control during swallowing. Claim 13 is similar and provides that the muscles are energized at the same time. Claims 17 is a similar method and provides that the muscles are energized at the same time with a signal generator capable of generating a complex pattern.

Claim 21 is directed to a system for coordinating the onset and offset of two or more different electrical signals used to coordinately control a bone, sphincter, tissue, structure or cartilage movement in the hypopharynx, or upper airway the system comprising a controller with a stored program that coordinates the onset and offset of two or more different electrical signals, an implantable signal generator, at least two intramuscular electrodes-operably connected to the signal generator, and a sensor device; wherein the controller under the direction of the stored program directs the signal generator to coordinate the onset and offset of two or more different electrical signals to activate each of the intra-muscular electrodes to move the bone, sphincter, tissue, structure or cartilage.

Claim 24 is directed to a system for moving a cartilage within an animal, comprising: a first electrode implanted in a first muscle attached to the cartilage or bone and operably connected to a signal generator; a second electrode implanted in a second different muscle attached to the same cartilage or bone and operably connected to the signal generator; and wherein the signal generator is implanted and generates a signal of about 10 to 75 Hz to the first and second electrodes at the same time; a switch operable by the animal that controls the signal generator, wherein the signal from the signal generator energizes the first and second muscles to effect a coordinated movement in the cartilage or bone that exceeds the movements made by pulses sent to the muscles at separate times.

Claim 28 is directed to a system for control of stimulation during swallowing of a human with dysphagia comprising: at least two intra-muscular electrodes; a signal generator connected to the at least two electrodes that outputs energy to the electrodes according to a determined pattern, a controller with a stored program that directs the signal generator to send electrical pulses to each of the at least two electrodes in the determined pattern, wherein the determined pattern of electrical pulses comprises a frequency of about 10 to 75 Hz and moves at least two

different muscles that control hyoid bone movement so that the hyoid bone moves forward and up; a power supply that provides energy for the signal generator; and a switch operable by the human that controls the signal generator, wherein the operation of the switch by the human directs the signal generator to send electrical pulses to each of the at least two electrodes embedded in muscle in the determined pattern.

Applicants submit that the cited references do not disclose all of the elements of the claims. With respect to the method claims, the Freed patent does not, in the least, describe intramuscular placement of electrodes or placement of electrodes into the thyrohyoid muscle and/or at least one hyoid muscle. The Freed patent is directed to external placement of electrodes on the skin and does not describe intramuscular stimulation of the muscles responsible for coordinated contractions that result in swallowing. In fact, surface stimulation does not reach the deep muscles such as the thyrohyoid that move the hyoid. There is also no disclosure in this patent regarding coordinated stimulation of at least two muscles that are targeted to move the hyoid bone and larynx resulting in protection of the airway which is an integral component of the swallowing process that prevents food or saliva from entering the larynx/airway.

Applicants also submit that the surface stimulation as applied by Freed, by contrast, results in movement of the hyoid bone *down* and movement of food or saliva into the airway. Applicants hereby submit the references in Appendix A that have been accepted and published by peer reviewed journals and that show that the surface stimulation of the Freed patent results in the movement of the hyoid bone down and ineffective swallowing.

With respect to the claim 28, Applicants submit that the Freed patent does not teach or suggest a system comprising a controller that has a stored program that directs the signal generator to send electrical pulses to each of the at least two electrodes embedded in muscle in the determined pattern, wherein the determined pattern of electrical pulses comprises a frequency of about 10 to 75 Hz and moves at least two different muscles that control hyoid bone movement so that the hyoid bone moves forward and up. As discussed previously, the application of the surface stimulation applied by Freed moves the hyoid bone down.

Moreover, Freed does not teach or suggest a switch operable by the human to control application of the signal. The system of Freed is directed to continuous but uncoordinated external stimulation of the tissue on the throat that cannot reach the pharyngeal tissue and would

not be effective if it was controlled by the patient. The continuous external stimulation of Freed does not benefit swallowing as it pulls the hyoid downward.

With respect to claim 21, the Freed patent does not teach or suggest a controller with a stored program that directs a signal generator to send electrical pulses to each of at least two electrodes embedded in muscle in the determined pattern, wherein the determined pattern of electrical pulses coordinates the onset and offset of two or more different electrical signals, each signal sent to a different electrode. Freed does not describe that the onset and offset of two different electrical signals is applied to two different electrodes embedded in muscle to coordinate control of the movement of the muscles. Since the electrodes of Freed are applied externally, the disclosure of Freed does not describe the coordinate control of two different muscles, each activated with a different signal to move the bone, sphincter, tissue, structure or cartilage. Freed also does not describe an implantable signal generator as the signals are applied only externally and the treatment is meant to be noninvasive.

With respect to claim 24, in the least, Freed does not disclose a switch operable by the human to control application of the signal. The system of Freed is directed to continuous external stimulation of the tissue on the neck surface and would not be effective if it was controlled by the patient as it produces movement opposite from the movement from that required for swallowing. The continuous external stimulation of Freed is directed to assisting the patient to relearn the swallowing motion.

The deficiencies of Freed are not remedied by reference to Sanders. Sanders is directed to opening the airway. The Sanders reference only describes a single muscle, the posterior cricoarytenoid muscle. When Sanders is read as a whole, it is directed to stimulation of a single muscle that opens rather than closes the airway. The signal parameters described in Sanders relate to restoring normal respiration by opening of the airway. There is no discussion in this reference of coordinating the offset and/or onset of signals to at least two different muscles. In addition, there is no discussion in this reference of applying signals that move at least two different muscles that control hyoid bone and thyroid cartilage movement so that the hyoid bone and larynx moves forward and up in the neck. In fact, it would be undesirable to move the hyoid bone and thyroid cartilage up and forward in Sanders as this would close the airway.

Moreover, if one of skill in the art combined the teachings of Freed and Sanders, swallowing would be made worse as Sanders teaches stimulation of a single muscle in order to open the airway. Opening the airway during swallowing would lead to aspiration of the material being swallowed. In addition, one of skill in the art would not know which muscles should be coordinated in order to provide for swallowing, as Sanders only describes a single muscle and Freed only describes external placement over many muscles. Manual stimulation as described in Sanders could not be applied to the methods described in Freed as continuous stimulation is necessary in Freed while the patient is attempting to relearn the swallowing motion even though the movement induced by the Freed stimulation on the skin surface interferes with swallowing. The Examiner has presented no evidence that activation of a signal by the patient as described in Freed would be sufficient to result in swallowing.

The Examiner has also presented no evidence that there would be a reasonable expectation of success that the appropriate muscles would be targeted, and that the appropriate signal parameters would be applied. There is no teaching or suggestion in the cited references as to which muscles should be targeted and the type of signals that would provide for coordinate control of at least two muscles to move the hyoid and larynx up so as to avoid aspiration. Swallowing is a complex movement requiring the coordination of at least two muscles. The examiner has not provided any evidence from the cited references that signals applied intramuscularly to at least two muscles would predictably result in swallowing. There are too many different variables that need to be changed from the combination of the cited references in order to achieve the claimed subject matter.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

**Summary**

Applicants submit that the claims of the present application are in condition for allowance and notification to that effect is earnestly solicited. The Examiner is invited to contact Applicants' representative at the telephone number listed below, if the Examiner believes that doing so will advance prosecution.

Respectfully submitted,

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